

#### Missouri Department of Health and Senior Services

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Matt Blunt

Julia M. Eckstein Director

September 27, 2005



John Madras Missouri Department of Natural Resources P.O. Box 176 Jefferson City, MO 65102-0176

Review of Draft Missouri Risk-Based Corrective Action Technical Guidance Document RE:

Dear Mr. Madras:

The Department of Health and Senior Services' (DHSS) Section for Environmental Public Health received a request from the Missouri Department of Natural Resources (MDNR) on September 13, 2005, to check the recent updates to the Draft Missouri Risk-Based Corrective Action Technical Guidance Document (MRBCA).

When the draft MRBCA guidance was developed, the Environmental Protection Agency's (EPA), Risk Assessment for Superfund (RAGS), Volume 1 – Human Health Evaluation Manual, Part E, Supplemental Guidance for Dermal Risk Assessment was not available. The draft MRBCA guidance still had the EPA RAGS, Part A equations prior to the recent update. In review of the equations and parameters in EPA RAGS, Volume I, Part E, 2004, DHSS has the following comments:

- 1. Section E.12 is missing the chemical specific parameters that are found in Appendix B, Exhibit B-3 of RAGS, Part E. A reference to these parameters for use in the dermal contact with organic chemicals in groundwater equation should be provided or the actual parameters provided in a table.
- 2. Section E.12 should mention that this equation applies only to organic chemicals.
- 3. The DA event condition statement "If t event < t\* equation" should be greater than or equal to, because there is not a condition where the event duration (t event) is equal to the time to reach steady state (t\*).
- The calculation of  $\tau_{event}$  uses the effective diffusion coefficient for chemical transfer through the stratum corneum (cm2/hr), which is chemical-specific, and uses the apparent thickness of stratum corneum. Will there be cases where these two values will be useful when calculating  $\tau_{event}$  for a particular chemical? We believe that DNR should not exclude this important information when providing explanations of the equations.
- 5. Also, RAGS, Part E states, "the above model assumes that all chemicals absorbed into the skin during the exposure event (t event) would eventually be absorbed into the systemic circulation, with the stratum corneum being the main barrier for most chemicals. For highly lipophilic chemicals, the viable epidermis can be a significant barrier for chemical transfer from the stratum corneum to the systemic circulation. When this occurs, the relative rate of desquamation of the stratum corneum and cell proliferation rate at the

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base of the viable epidermis contribute to a net decrease in the total amount of absorbed chemical. For similar reasons, stratum corneum desquamation can reduce the amount of absorption for chemicals that are not highly lipophilic but large enough (high MW) that penetration through the stratum corneum is slow (i.e., lag times are long)." DHSS believes more explanation of the lag time parameter ( $\tau_{event}$ ) should be included to provide the risk assessor information needed for highly lipophilic chemicals.

6. Finally, parameters b and c in the calculation of  $\tau_{event}$  need to be defined.

In review of the toxicity value updates found in Handout 1 from the August 2005 Workgroup meeting, we have the following additional changes to make to the recommended toxicity changes on Handout 1. Several of our recommended changes below were made as comments in our March 21, 2005 letter to MDNR (see list below for an explanation of acronyms):

Chemical Name	CASRN	DHSS Recommended Change	Source	Comment
1,2-dibromo-3- chloropropane	96-12-8	RfD <sub>i</sub> : 5.7E-5 mg/kg-day	IRIS	March 21, 2005 letter
1,3- dichloropropene	542-75-6	RfD <sub>o</sub> : 3.0E-2 mg/kg-day RfD <sub>i</sub> : 5.7E-5 mg/kg-day	IRIS IRIS	Updated values are incorrect. MDNR should use the hierarchy of toxicity sources.
tetrachloroethylene	127-18-4	RfD <sub>i</sub> : 1.0E-2 mg/kg-day	CalEPA	Updated value is incorrect. MDNR should use the hierarchy of toxicity sources.
1,1-dichloroethane	75-34-3	RfD <sub>i</sub> : 1.4E-2 mg/kg-day	HEAST	March 21, 2005 letter
1,2- dichlorobenzene	95-50-1	RfD <sub>i</sub> : 5.7E-3 mg/kg-day	HEAST	March 21, 2005 letter
n-butylbenzene	104-51-8	RfD <sub>o</sub> : 1.0E-2 mg/kg-day	RAIP 97-009/6-5-97	March 21, 2005 letter
sec-butylbenzene	135-98-8	RfD <sub>o</sub> : 1.0E-2 mg/kg-day	RAIP 97-009/6-5-97	March 21, 2005 letter
tert-butylbenzene	98-06-6	RfD <sub>o</sub> : 1.0E-2 mg/kg-day	RAIP 97-009/6-5-97	March 21, 2005 letter
n-propylbenzene	103-65-1	RfD <sub>o</sub> : 1.0E-2 mg/kg-day	RAIP 97-009/6-5-97	March 21, 2005 letter

Acronym list:

RAIP: Risk Assessment Issue Papers

HEAST: Health Effects Assessment Summary Tables. CASRN: Chemical Abstract Service Registration Number.

IRIS: Environmental Protection Agency Integrated Risk Information System.

CalEPA: California Environmental Protection Agency.

RfD<sub>i</sub>: Inhalation reference dose. RfD<sub>o</sub>: Oral reference dose. Page 3 John Madras 9/27/05

Originally, for 3-nitroaniline, DHSS recommended a reference dose for inhalation (RfDi) of 3.0 E-4 mg/kg day; however, according to the EPA Region 9 Preliminary Remediation Goal's, the oral reference dose (RfDo) and also the RfDi should be 2.1 E-02. MDNR should use the 3.0 E-4 mg/kg day RfDi because this value is within the Workgroup hierarchy of toxicity value sources listed at the bottom of Handout 1 from the August 2005 Workgroup meeting.

For carbazole, the EPA Cancer Group is B2, according to EPA's Integrated Risk Information System (IRIS).

Thank you for the opportunity to comment on the draft guidance document. If you have any questions, please feel free to contact Todd Blanc at (573) 751-6160.

Gale Carlson, Unit Chief

Section for Environmental Public Health

cc: Linda Vogt, DNR Andrew McKinney, DHSS

TJB/GC/jmd

Electronic copy of letterhead

# STATE OF MISSOURI DFPARTMEN

Matt Blunt, Governor • Doyle Childers, Director

### DEPARTMENT OF NATURAL RESOURCES

www.dnr.mo.gov

Mr. Gale Carlson Section for Environmental Health Department of Health and Senior Services P.O. Box 570 Jefferson City, MO 65102-0570

Dear Mr. Carlson:

Thank you for your letter and comments of March 21, 2005, on the revised Departmental Missouri Risk-Based Corrective Action Technical Guidance. As you know, the guidance is a complex document, and we appreciate your assistance in ensuring its accuracy. We are providing the following responses.

1. DHSS Comment #1: Section E.12 is missing the chemical specific parameters that are found in Appendix B, Exhibit B-3 of RAGS, Part E. A reference to these parameters for use in the dermal contact with organic chemicals in groundwater equation should be provided or the actual parameters provided in a table.

DNR Response: To date, we have not revised this section to include RAGS Part E considerations. Table E-1 will be revised to include the "new" chemical-specific parameters related to dermal contract pathway when all input parameters have been finalized.

2. Section E.12 should mention that this equation applies only to organic chemicals.

DNR Response: The updated Section E.12 (page E-16) specifies which equation is for organic and which is for inorganic chemicals.

3. The DA event condition statement "If  $t_{event} < t^*$  equation" should be greater than or equal to, because there is not a condition where the event duration ( $t_{event}$ ) is equal to the time to reach steady state ( $t^*$ ).

DNR Response: We will make this change.

4. The calculation of  $\tau_{event}$  uses the effective diffusion coefficient for chemical transfer through the stratum corneum (cm2/hr), which is chemical-specific, and uses the apparent thickness of stratum corneum. Will there be cases where these two values will be useful when calculating  $\tau_{event}$  for a particular chemical? We believe that DNR should not exclude this important information when providing explanations of the equations.

### DNR Response: The calculation of $\tau_{event}$ will be discussed in Appendix E when we revise Appendix E.

5. Also, RAGS, Part E states, "the above model assumes that all chemicals absorbed into the skin during the exposure event ( $t_{event}$ ) would eventually be absorbed into the systemic circulation, with the stratum corneum being the main barrier for most chemicals. For highly lipophilic chemicals, the viable epidermis can be a significant barrier for chemical transfer from the stratum corneum to the systemic circulation. When this occurs, the relative rate of desquamation of the stratum corneum and cell proliferation rate at the base of the viable epidermis contribute to a net decrease in the total amount of absorbed chemical. For similar reasons, stratum corneum desquamation can reduce the amount of absorption for chemicals that are not highly lipophilic but large enough (high MW) that penetration through the stratum corneum is slow (i.e., lag times are long)." DHSS believes more explanation of the lag time parameter ( $\tau_{event}$ ) should be included to provide the risk assessor information needed for highly lipophilic chemicals.

#### DNR Response: We will add the explanation in Appendix E when we revise Appendix E.

6. Finally, parameters b and c in the calculation of  $\tau_{event}$  need to be defined.

#### DNR Response: We will define b and c in Section E.12 as follows:

## b,c = Correlation coefficient which have been fitted to the data from Flynn, G.L. (1990)

In review of the toxicity value updates found in Handout 1 from the August 2005 Workgroup meeting, we have the following additional changes to make to the recommended toxicity changes on Handout 1. Several of our recommended changes below were made as comments in our March 21, 2005 letter to MDNR (see list below for an explanation of acronyms):

<b>Chemical Name</b>	CASRN	DHSS	Source	Comment
		Recommended		
		Change		
1,2-dibromo-3-	96-12-8	RfD <sub>i</sub> : 5.7E-5	IRIS	March 21, 2005 letter
chloropropane		mg/kg-day		
1,3-	542-75-6	RfD <sub>o</sub> : 3.0E-2	IRIS	Updated values are
dichloropropene		mg/kg-day	IRIS	incorrect. MDNR
		RfD <sub>i</sub> : 5.7E-5		should use the
		mg/kg-day		hierarchy of toxicity

				sources.
tetrachloroethylene	127-18-4	RfD <sub>i</sub> : 1.0E-2	CalEPA	Updated value is
		mg/kg-day		incorrect. MDNR
				should use the
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1,1-dichloroethane	75-34-3	RfD <sub>i</sub> : 1.4E-2	HEAST	March 21, 2005 letter
		mg/kg-day		
1,2-	95-50-1	RfD <sub>i</sub> : 5.7E-3	HEAST	March 21, 2005 letter
dichlorobenzene		mg/kg-day		
n-butylbenzene	104-51-8	RfD <sub>o</sub> : 1.0E-2	RAIP	March 21, 2005 letter
		mg/kg-day	97-009/6-5-97	
sec-butylbenzene	135-98-8	RfD <sub>o</sub> : 1.0E-2	RAIP	March 21, 2005 letter
		mg/kg-day	97-009/6-5-97	
tert-butylbenzene	98-06-6	RfD <sub>o</sub> : 1.0E-2	RAIP	March 21, 2005 letter
		mg/kg-day	97-009/6-5-97	
n-propylbenzene	103-65-1	RfD <sub>o</sub> : 1.0E-2	RAIP	March 21, 2005 letter
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Originally, for 3-nitroaniline, DHSS recommended a reference dose for inhalation (RfDi) of 3.0 E-4 mg/kg day; however, according to the EPA Region 9 Preliminary Remediation Goal's, the oral reference dose (RfDo) and also the RfDi should be 2.1 E-02. MDNR should use the 3.0 E-4 mg/kg day RfDi because this value is within the Workgroup hierarchy of toxicity value sources listed at the bottom of Handout 1 from the August 2005 Workgroup meeting.

For carbazole, the EPA Cancer Group is B2, according to EPA's Integrated Risk Information System (IRIS).

#### **DNR Response:**

- 1,2-dibromo-3-chloropropane: DHSS is correct. We will update value.
- 1,3-dichloropropene: We will accept an RfDo of 3.0E-02. However, the RfDi should be 5.7E-03, not 5.7E-05.
- Tetrachloroethylene: The RfDi of1.0E-02 is from the state of Texas, and the source of its information is the Agency for Toxic Substances and Disease Registry (ATSDR). CalEPA does not contain a value for this reference dose.
- 1,1-dichloroethane: EPA Region IX PRG Table gives RfDi of 1.4E-01 not 1.4E-02. DHSS indicated that this value is not from HEAST but from a paper published by

EPA's National Center for Environmental Assessment (NCEA). Because this source is higher on our hierarchy, we will update this value

- 1,2-dichlorobenzene: DHSS retracted this comment.
- n-butylbenzene, sec-butylbenzene, ter-butylbenzene, and n-propylbenzene: For these four chemicals from RAIP, the current MRBCA values are correct based upon our heirarchy of sources.
- 3-nitroaniline: This value was updated correctly with an RfDi of 3.0E-04.
- carbazole: We have deleted the EPA Cancer Group entirely from Table E-1 as it provides little useful information.

Again, thank you for your assistance. We trust that we have responded to your comments, but if you have any further questions or concerns, please contact me at 573-751-6998.

Sincerely,

HAZARDOUS WASTE PROGRAM

Original signed by Linda Vogt

Linda Vogt Environmental Specialist IV

LV:jc